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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/098,644	03/15/2002	Susan A. Gregory	C2916/4 (PHA 4151.7)	7986

321 7590 05/16/2005

SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
SEAMAN, D MARGARET M	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/098,644	GREGORY ET AL.	
	Examiner	Art Unit	
	D. Margaret Seaman	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-20 and 22-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *20 and 22-38* is/are allowed.

6)☒ Claim(s) *10-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RP

DETAILED ACTION

This application was filed 15 March 2002. Claims 10-20 and 22-38 are before the Examiner.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the claims are drawn to a composition of three items, the third of which is an immunosuppressive drug selected from antiproliferation agents, anti-inflammatory-acting compounds and inhibitors of leukocyte activation. However, aspirin is a well known anti-inflammatory-acting compound but aspirin is not known as an immunosuppressive drug. Is the immunosuppressive drug also known as an anti-inflammatory-acting drug or is the anti-inflammatory-acting drug also an immunosuppressive drug? The only drugs enabled by the instant specification are those drugs specifically identified in the specification. The ordinary artisan would not be able to determine the meaning of the third component of the instantly claimed composition by the

definition in the claims. Due to this, the only definition left would be the compounds identified in the specification.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 10-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is not seen where the instant specification provides the written description of the claimed invention of a composition of a COX-2 inhibitor, a 5-lipoxygenase inhibitor and an immunosuppressive drug wherein the immunosuppressive drug is selected from antiproliferation agents, anti-inflammatory-acting compounds and inhibitors of leukocyte activation. The specification does not fully describe the connection between the immunosuppressive drug and antiproliferation agents, anti-inflammatory-acting compounds and inhibitors of leukocyte activation. Is the immunosuppressive drug also an anti-inflammatory agent? Is the anti-inflammatory agent also an

immunosuppressive drug? Or is the immunosuppressive drug an anti-inflammatory agent (such as aspirin) being used as an immunosuppressive drug?

Further, the instant specification discloses a hoped-for function (composition) for as-yet-to-be-discovered compounds and a research plan for trying to find these compositions. The specification contains a description as to what can be done with any compounds that can potentially be identified as COX-2 inhibitors, 5-lipoxygenase inhibitors or immunosuppressive drugs. However, the specification does not disclose which compounds have the desired characteristic for inhibiting COX-2, 5-lipoxygenase or immunosuppressive ness. The instant claims do not disclose structures or identities of compounds that are COX-2 inhibitors, 5-lipoxygenase inhibitors or immunosuppressive drugs all within the same claim. Claims under this rejection either contain no structure disclosure (for immunosuppressive drugs) or only limited structure or such as claim 17 contains only a description for the 5-lipoxygenase inhibitor and the Cox-2 inhibitor.

Applicant argues that describing distinguishing identifying characteristics sufficient to show that he applicant was in possession of the claimed invention. However, MPEP 2163 further states "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and

formulas that fully set forth the claimed invention. Lockwood v.American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997)."

5. Claims 10, 11 and 18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is seen as not enabling for the instant claims because the claims are drawn to a composition containing several active ingredients.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims: The claims are drawn to a composition containing any and all known and unknown COX-2 inhibitors, 5-lipoxygenase inhibitors and immunosuppressive drugs.

3) The state of the prior art: The art knows of drugs that are independently COX-2 inhibitors, 5-lipoxygenase inhibitors and immunosuppressive drugs. The art also knows of combinations of two or more of these active ingredients.

5) The level of predictability in the art: With the three-dimensional structures of the enzymes such as COX-2, it is not within the skill of the ordinary artisan to predict what compounds might bind to and inhibit them (University of Rochester v. G.D.Searle & Co. (CAFC 03-1304)).

6) The amount of direction provided by the inventor: The instant specification does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to make or carry out the claimed compositions. One of ordinary skill in the art would have to find a compound, determine what activity it may have, and then put it into a composition with other active ingredients that have yet to be determined

7) The existence of working examples: The art is aware of individual compounds that are either immunosuppressant drugs or COX-2 or 5-lipoxygenase inhibitors. However, the examples are a few currently known compounds compared to the vast number of unknown or undiscovered compounds that potentially exist.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The practice of making the claimed compositions would require a person of ordinary skill in the art to engage in undue experimentation, with no assurance of success.

The specification does not provide any guidance with respect to how to make the compounds. The only way to identify the characteristics necessary for recognizing that a compound is a candidate for the instant claims is the activity. That activity must be determined and then the possible compounds must be mixed with other active compounds. Further, with the definition of immunosuppressive drug selected from antiproliferation agents, anti-inflammatory-acting compounds and inhibitors of leukocyte activation, it is unclear as to what compounds fit within the definition of immunosuppressive drug other than those specified in the specification. The selection of compounds is not enabled by the instant specification.

Taking the above into consideration, it is not seen where the instant specification enables the ordinary artisan to make or use the instant invention with any and all COX-2 inhibitor, 5-lipoxygenase inhibitor or an immunosuppressive drugs.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone

number is 571-272-0694. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms